State of Louisiana
Department of Health and Hospitals
Office of Public Health

Laboratory Guidance
Pandemic Influenza Response

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FINAL

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I. Laboratory Plan Overview

The Louisiana Department of Health and Hospitals (DHH) Office of Public Health (OPH) has created this Pandemic Influenza Guidance as a comprehensive containment and treatment plan to assist in the control of an outbreak of a novel influenza virus, such as the 2009 H1N1 influenza virus ("swine flu") or avian influenza. DHH OPH has followed, and will continue to follow, the international and national recommendations[i],[ii],[iii] for identification, prophylaxis, and treatment of disease as well as considered the frameworks provided by the Centers for Disease Control and Prevention (CDC) for pandemic planning purposes[iv],[v] as well as those recommended by the Occupational Safety and Health Association (OSHA)[vi]. This Laboratory Plan also serves as an Annex to the Louisiana Pandemic Influenza Guidance, which describes the overall response for the Department of Health and Hospitals.

As there is little natural immunity to any new virus, it is recognized by DHH OPH that ongoing communications and updates to the health care community as well as the public are critical to the health of Louisiana. The recommendations that identify vulnerable populations and guidelines for treatment[vii],[viii],[ix],[x],[xi] are also adopted by Louisiana, and the State remains in compliance with recommendations from such authorities as the Centers for Disease Control and Prevention (CDC).

Mission

To provide quality clinical and environmental laboratory services throughout Louisiana**.**

Command and Control

National Incident Management

This Pandemic Influenza Guidance is compatible with the State of Louisiana Emergency Operations Plan[xii]. Further, it is compliant with National Response Framework[xiii], which requires the organization of response according to the National Incident Management System (NIMS). Operations are conducted using the Incident Command System (ICS).

During an emergency or disaster, some administrative procedures may be suspended, relaxed, or made optional. Such action will be carefully considered, and the consequences should be projected realistically. Departures from usual guidelines will be stated in the Governor's State of Emergency Order and in emergency plans or guidelines.

Lead Agency

DHH OPH[xiv] is the lead agency in the Pandemic Influenza Response within Louisiana. DHH works collaboratively with several State, local, and private agencies to provide trainings and other educational opportunities to ensure preparedness in a pandemic situation. Any meetings and exercises, however, also contribute to the success of State operations and training programs in that they ensure a variety of educational opportunities are available for the Pandemic Influenza Response topics.

Roles and Responsibilities

The Office of Public Health Laboratory is a functional member of the Laboratory Response Network. The State OPH Laboratory Director or designee will coordinate communication with the State Epidemiologist or designee and the Center for Community Preparedness Director or designee.

II. Planning Section

Preparedness

The State constantly seeks opportunities to work with local partners and assist with event-specific planning. As various aspects of this Plan have been exercised or drilled in accordance with the Louisiana Emergency Operations Plan (EOP), this provides a strong community response and cooperation.

The DHH OPH office has identified persons to lead, plan, and oversee the training, exercise, and evaluation components of various preparedness programs. There are regional counterparts for each of these positions. The regions coordinate and receive guidance from the Louisiana DHH OPH. Coordination occurs within regions and parishes to provide guidance of upcoming and future training activities as well as event-specific training and exercise plans (updated annually). The multi-year plan is HSEEP compliant, and uses local, parish, and region-wide exercises to test knowledge post-training, and lessons learned are incorporated into the Action Request Form (ARF) or IAP form 308[xv] through an ongoing review process. A portion of pandemic response will be tested annually.

Identification of Pandemic Influenza Cases

Each strain of novel influenza will most likely present in a similar fashion.

Methods of Information Exchange

The Louisiana Office of Public Health Laboratory Emergency Response Coordinator and Laboratory Bioterrorism Program Advisor will be liaisons from LA Office of Public Health Laboratory to the clinical laboratories and other laboratories performing novel influenza virus testing. The LA Office of Public Health Laboratory maintains a contact list for clinical laboratories throughout Louisiana, and when necessary can distribute updated information by BLAST FAX, email, letter, and/or posting on the LA Office of Public Health Laboratory website.

As a component of Laboratory pandemic influenza planning, electronic reporting of influenza results will be submitted to the Office of Public Health.

The LA Office of Public Health Laboratory is in the process of installing a comprehensive Laboratory Information Management System (LIMS) in its four laboratories. The vendor (Starlims, Inc.) was selected through an exhaustive RFP process. Requirements that were delineated in the RFP, and which the Starlims' LIMS must meet include:

1. The LIMS must be installed in all four Office of Public Health laboratories, and it must be capable of integrating with other OPH software.
2. The LIMS must come with a web component so that tests can be ordered and reported electronically.
3. The LIMS must be capable of sending reports and data automatically to multiple submitters, program staff, agency personnel, and external partners (e.g., CDC) using secure protocols.

4. The LIMS must be compliant with the Public Health Information Network (PHIN) standards established by the Centers for Disease Control and Prevention (CDC). These standards include the creation of files in the HL7 format. A key component of HL7 includes the use of the standard code sets known as LOINC and SNOMED for reporting results and identifying procedures.
5. The LIMS must be capable of creating, storing and accepting data from and to HL7 messages or standard file formats containing standard terminology (e.g., LOINC and SNOMED) for test submittals that submitters can map to/from their system databases.
6. The LIMS must have the ability for electronic reports to be sent in a secure format (such as ebXML format using Public Key Infrastructure (PKI) encryption) conforming to PHIN and HIPAA standards for privacy and security.

Submitters will be able to receive results by fax as well as electronically. In the future they will be able to order tests and access results via the web component. The OPH Section of Laboratory Services will be able to automatically send test results to multiple clients, including OPH Infectious Disease Epidemiology and the CDC.

Call-down procedures

In the event of a pandemic the LA Office of Public Health Laboratory in Metairie is prepared to augment the testing capabilities of that facility to accommodate the expected increase in specimen volume submitted by clinical laboratories. All personnel capable of performing the required testing are noted on a standby roster with contact numbers. These individuals will be required to work extended shifts in order to maintain 24 hour testing, 7 days a week.

The LA Office of Public Health Laboratory updates employee contact information on a quarterly basis. The information obtained during this update process is used to create emergency-specific call-down lists. During an emergency, the LA Office of Public Health Laboratory Director, the Laboratory Assistant Director or the Laboratory Emergency Response Coordinator will notify the Laboratory Manager of each section by phone. The Laboratory Managers in turn will contact the supervisors of the laboratories that fall under their jurisdiction. The Laboratory Supervisors will then notify the Laboratory Scientists in their labs of where and when they are expected to report to work.

Additional Laboratory Facilities

At the current time, all influenza samples are being tested at the LA Office of Public Health Central Laboratory in Metairie. In the event that additional influenza testing capacity is required, it will be performed at the LA Office of Public Health Laboratory in Shreveport. Current plans include obtaining additional equipment to facilitate this goal. Personnel at the LA Office of Public Health Laboratory in Shreveport will be trained in the required testing protocols.

The LA Office of Public Health Laboratory, at the present time, is exploring the option of using different real time PCR platforms and optimizing the existing pandemic influenza testing protocol to work on the equipment that is being used in our laboratory at this time. Once these protocols are validated on the new testing platforms, the LA Office of Public Health Laboratory's influenza testing capacity will increase significantly since we have this equipment in place at both the Office of Public Health Central Laboratory and the Shreveport Regional Laboratory. This will allow for additional surge capacity in the event of a pandemic influenza outbreak in Louisiana.

Documentation

Incident Action Report (IAP)

Under NIMS, the appropriate method of tracking operational objectives, logistics movements, and safety issues is through the Incident Action Plan (IAP)[xvi]. Through the assistance of the DHH OPH Documentation Coordinator at the DHH Emergency Operations Center, the DHH OPH Planning Section will be able to complete the appropriate sections of the IAP to track requests for assets, distribution of inventory, and documentation of communications with RSS or regional staff regarding antiviral dispensing sites.

An IAP must be created for every operational period, which may fluctuate as the event and response unfolds. IAPs are typically created for a 12-hour operational period, but may be created for shorter periods of time. IAPs may be created for operational periods up to 24-hours once an event/response has been underway for some time.

While Louisiana and the federal government do not guarantee any reimbursement for resources used during a response, in the event that reimbursement becomes available, it will be important that accurate and comprehensive documentation be available. The IAP is a generally accepted mechanism for accurately and adequately tracking situational information.

III. Operations Section

Concept of Operations by Interval

This Laboratory Plan is an Annex of the Pandemic Influenza Guidance, which was created with a cooperative management concept. While there is a single point (State Health Officer) to obtain and disseminate key medical-related information, many of the other requirements of the program are supported by other State agencies at various stages of the pandemic. Planning, emergency management, prevention, preparedness, response, recovery, and mitigation discussions are facilitated by DHH OPH and use subject matter experts for relevant contributions.

DHH OPH has determined that the most efficacious use of resources occurs with "interval" planning. The Intervals for Pandemic Influenza Response (including the Louisiana and national triggers) is listed as Table 1, included in Section VIII. Supporting Documents. It is noted that due to the rapid spread of a novel influenza, several of these pandemic intervals may seem to occur concurrently to one another.

It should be noted that the Lab conducts surveillance year-round for seasonal influenza. This falls outside of the pandemic intervals or pandemic periods, but is an activity that is integral in the identification of novel influenza.

Lab Responsibilities during this non-pandemic cycle or time frame focus on the following:

The LA Office of Public Health Laboratory provides laboratory support for seasonal influenza surveillance in Louisiana. The goal of seasonal virologic surveillance is to provide laboratory confirmation of the first cases of influenza in regional areas to track influenza activity each season. To support seasonal influenza surveillance, the LA Office of Public Health Laboratory provides virologic testing for respiratory specimens submitted by physicians in the Sentinel Provider Network and by the LA Office of Public Health Infectious Disease Disease Epidemiology section for outbreak investigations. The LA Office of Public Health Laboratory provides influenza and respiratory virus testing throughout the year. Nasopharyngeal swab specimens are routinely tested by nucleic acid amplification detection of influenza virus types A or B, with influenza A subtyping for H1, H3 and H5 by real time reverse transcriptase polymerase chain reaction (RT-PCR). The RT-PCR test results can be completed on the same day that the specimen is received.

At this time, the LA Office of Public Health Laboratory is not able to perform virus culture. If additional trained laboratory staff is hired, the LA Office of Public Health Laboratory will resume viral culture and isolation. At this time, all specimens will be sent to the CDC if further testing is required.

Final LA Office of Public Health laboratory results of influenza testing are reported by fax or mail to the specimen submitter and to Louisiana Office of Public Health Infectious Disease Epidemiology section. For outbreak investigations, positive RT-PCR results are faxed to the submitter, usually on the same day the specimen is received at LA Office of Public Health Laboratory. The LA Office of Public Health Laboratory has implemented its laboratory

information system (STARLIMS) and reports are faxed automatically to the submitter when samples are released.

Immediately upon notification of a threat or an imminent or actual incident, the following actions will be taken, as required, according to the Interval structure by the Lab.

Investigation and Recognition

During the pandemic alert period (in the Investigation Interval), if a patient meets the current CDC and LA Office of Public Health clinical and epidemiological criteria for possible infection by a novel influenza subtype, clinical specimens may be submitted to the LA Office of Public Health Laboratory for testing. It is essential that the health care provider contact the state epidemiologist and the LA Office of Public Health Laboratory to assure appropriate specimen collection, transport, and testing. Specimens must be identified as "test for novel influenza" to ensure that the necessary level of biosafety is used and that appropriate testing is performed.

At the present time, the LA Office of Public Health Laboratory performs real time reverse transcription polymerase chain reaction (RT-PCR) to detect and subtype influenza virus in direct specimens but does not have the biocontainment level (BSL-3 with enhancements) needed to culture novel influenza subtypes. Therefore, a clinical specimen from a patient suspected of infection with a novel influenza subtype would be screened by real time RT-PCR for influenza viruses A and B, and for influenza A subtypes H1 and H3 (the currently circulating subtypes of human influenza virus) and subtype H5 (the avian subtype involved in the current epizootic among poultry in Asia). This method can provide results on the same day the specimen is received at the LA Office of Public Health Laboratory. Testing at the LA Office of Public Health Laboratory for other influenza A subtypes such as H7 will be added as positive control material is made available to the state public health laboratories by CDC or other federal partners.

If a clinical specimen were to test positive at the LA Office of Public Health Laboratory by real time RT-PCR for a novel influenza subtype, the results would immediately be reported to the LA Office of Public Health Infectious Disease Epidemiology section. The specimen would then be forwarded to CDC for viral culture and confirmatory testing if required. If the specimen tested positive for one of the currently circulating seasonal influenza viruses, then the Office of Public Health Infectious Disease Epidemiology section will be notified. If the specimen tests negative for influenza viruses A and B by RT-PCR, then the need for additional testing will be determined in consultation with the LA Office of Public Health Infectious Disease Epidemiology section.

Detection and characterization of novel influenza strains

The LA Office of Public Health Laboratory has incorporated real time RT-PCR testing into its standard influenza laboratory testing activities, using CDC methods posted on the Association of Public Health Laboratories (APHL) website. Current LA Office of Public Health Laboratory methods detect influenza A or influenza B, and identify influenza A subtypes H1, H3 or H5 directly from clinical specimens (such as nasopharyngeal swabs submitted in viral transport media). Testing for other novel influenza A subtypes such as H7 will be made available at the LA Office of Public Health Laboratory when procedures and positive control materials are released by federal partners and test performance is validated at the LA Office of Public Health Laboratory. The LA Office of Public Health Laboratory will continue to evaluate and develop new laboratory methods to detect and characterize influenza virus as opportunities present. At this

time, a positive RT-PCR result for a novel influenza A subtype such as H5 would be considered presumptive, pending culture and confirmation at CDC. The LA Office of Public Health Laboratory will work with the LA Office of Public Health Infectious Disease Epidemiology section to provide healthcare providers, hospitals, and clinical laboratories within Louisiana the information on how to contact the LA Office of Public Health Laboratory when a novel influenza subtype is suspected; how to handle, label, and ship clinical specimens for diagnostic evaluation from these cases; and how to notify the Office of Public Health.

The LA Office of Public Health Laboratory will work to identify and contact other laboratories in Louisiana which may conduct influenza testing or culture influenza viruses (e.g. research, veterinary, agricultural, or private industry laboratories) to provide information about the guidelines in the national and state pandemic influenza plans, especially the need for biocontainment, medical surveillance of laboratory personnel, and how and when to report situations to the LA Office of Public Health and to the LA Office of Public Health Laboratory.

Laboratory reporting

The LA Office of Public Health Laboratory would report cases of novel influenza immediately to the LA Office of Public Health Laboratory Director, the Office of Public Health Infectious Disease Epidemiology section and to CDC via the Emergency Response Hotline, if required.

The LA Office of Public Health Laboratory planning for pandemic influenza will include electronic reporting of influenza results to above mentioned Office of Public Health sections and submitters as the LA Office of Public Health Laboratory implements its laboratory information system (STARLIMS).

Distribution of diagnostic reagents and test information

The LA Office of Public Health Laboratory and other state public health laboratories remain dependent on federal partners such as CDC to address any regulatory barriers to emergency distribution and use of diagnostic tests and reagents during a pandemic. The responsibility of the LA Office of Public Health Laboratory is to stay updated about upcoming test information and to position the LA Office of Public Health laboratory resources so that as soon as a new procedure or critical reagent is released by the CDC, the LA Office of Public Health Laboratory can begin validation studies and rapid implementation of diagnostic testing at the state level.

Laboratory surge capacity planning

The LA Office of Public Health Laboratory will assess the projected statewide needs for scaled-up diagnostic activity during the early stages of a pandemic and develop strategies to meet those needs as effectively as possible. The LA Office of Public Health Laboratory will work with the LA Office of Public Health to estimate testing needs for Louisiana, and to establish proposed goals for testing priorities, so that limited resources will be targeted toward testing the specimens most important for public health planning (e.g. to identify the first cases, or to verify regional spread of the pandemic strain within the state). The LA Office of Public Health Laboratory will also plan with the LA Office of Public Health to create proposed trigger points for making changes in the testing algorithm (e.g. the point at which the pandemic strain is circulating so widely that influenza testing at the state public health lab should be cut back to more routine surveillance support activities). The LA Office of Public Health Laboratory will estimate the surge capacity needed for staff and training, supplies/equipment, and specimen

management, develop strategies to address these needs, and track progress toward implementation of this surge capacity plan.

Partnerships with healthcare providers and clinical laboratories

The LA Office of Public Health Laboratory will continue to build partnerships with healthcare providers within Louisiana, including the physicians who participate in the Sentinel Provider Network during the regular influenza season.

The LA Office of Public Health Laboratory will continue to build partnerships with clinical laboratories within Louisiana and provide laboratories with updated information as it becomes available. The LA Office of Public Health Laboratory Emergency Response Coordinator will be a liaison from LA Office of Public Health Laboratory to the clinical and local public health laboratories. The LA Office of Public Health Laboratory maintains a contact list for clinical laboratories throughout Louisiana, and when necessary can distribute updated information by BLAST FAX, email, letter, and/or posting on the LA Office of Public Health Laboratory website.

Initiation, Acceleration, and Peak/Established Transmission

During a pandemic, the goals of virologic surveillance are to:

- Rapidly detect the introduction and early cases of a pandemic influenza in the United States
- Track the introduction of the virus into local areas
- Monitor changes in the pandemic virus, including development of antiviral resistance

The LA Office of Public Health Laboratory will provide laboratory support for pandemic influenza surveillance through the same mechanisms that support laboratory-based surveillance for seasonal influenza except that the testing algorithms may be modified due to biosafety considerations or the need to target limited resources toward testing required for public health decisions. RT-PCR methods currently performed at the LA Office of Public Health Laboratory can detect influenza A or influenza B virus and identify the influenza A subtypes H1, H3, and H5. According to the HHS national pandemic influenza plan, as soon as a pandemic strain of influenza virus has been identified, CDC's Influenza Laboratory will develop, produce, and disseminate the necessary RT-PCR and DFA/IFA reagents to state public health laboratories such as the LA Office of Public Health Laboratory. If necessary, CDC and APHL will also update the RT-PCR protocol currently available to public health laboratories through the APHL website. When the diagnostic procedures and reagents are made available by CDC to the state public health laboratories, the LA Office of Public Health Laboratory will validate and implement RT-PCR testing specifically for the pandemic strain. During the time period before CDC would be able to provide pandemic strain specific reagents to the state public health laboratories, the LA Office of Public Health Laboratory would continue to test for the influenza A virus subtypes for which reagents are already available. Such testing would provide rapid test results to identify infections with an Influenza A virus other than one of the subtypes in the current testing battery, and would thus alert surveillance to the probable presence of a novel influenza subtype. The exact subtype would not be identified until further testing could be performed at CDC.

When a pandemic first begins, laboratory testing to confirm the new subtype will be required. The most intense testing will be during the early stages of the pandemic when the primary goal

is to verify whether the new virus has been introduced into the state or community. Once the virus has been identified throughout the state, the level of laboratory testing can be decreased to a level more like that of a non-pandemic influenza season. CDC will provide guidelines on when confirmatory testing (i.e. subtyping of influenza A virus) is required. The LA Office of Public Health Infectious Disease Epidemiology section will work with the LA Office of Public Health Laboratory to determine the level of testing needed within Louisiana, and to help prioritize laboratory testing needs. At the beginning of a pandemic, it will be critical that public health needs are met by appropriately prioritizing specimen submissions and testing at the LA Office of Public Health Laboratory; otherwise, the surge of specimens might rapidly deplete limited and valuable reagents. Prioritization decisions will require input from the LA Office of Public Health Infectious Disease Epidemiology section about data needed for public health decisions and from the LA Office of Public Health Laboratory about the supply inventory, consumption of supplies, and availability of laboratory personnel.

As the pandemic continues, the LA Office of Public Health Laboratory will follow CDC guidance to the states on the percentage of isolates/specimens per week or month that the state public health laboratories should send to CDC to help monitor changes in the antigenicity and antiviral susceptibility of the pandemic virus. Throughout the pandemic, CDC will provide updated instructions on the collection of clinical and epidemiologic data that should accompany isolates/specimens. The LA Office of Public Health Infectious Disease Epidemiology section will work with the LA Office of Public Health Laboratory to create a mechanism by which this data will accompany isolates submitted by the LA Office of Public Health Laboratory to CDC. The LA Office of Public Health Laboratory is currently positioned to be able to provide RT-PCR screening before sending specimens to CDC, if reagents and procedures are made available for the pandemic strain.

Laboratory Support for Clinicians

When a pandemic begins, public health and clinical laboratories will need to manage increased numbers of requests for influenza testing. CDC will work with state public health laboratories and the LRN to provide clinical laboratories with guidelines for safe handling, processing, and rapid diagnostic testing of clinical specimens from patients who meet the case definition of pandemic influenza. The LA Office of Public Health Laboratory will provide clinical laboratories within Louisiana with these CDC guidelines using the mechanisms created by Emergency Preparedness and Response (EP&R) planning such as BLAST FAX, email, letter, or website posting. Guidance will be provided to clinicians about the case definition of pandemic influenza and which subset of patients should have specimens sent to the LA Office of Public Health Laboratory for pandemic influenza testing. The LA Office of Public Health Laboratory will provide local healthcare providers with specimen submission forms that specify the clinical and epidemiologic data that should accompany specimens sent to the LA Office of Public Health Laboratory for pandemic influenza testing.

For pandemic influenza, the LA Office of Public Health Laboratory will have to plan, implement, and test methods for rapid communication of both positive and negative results to the submitter, to the LA Office of Public Health Infectious Disease Epidemiology section, and to the Statewide Influenza Coordinator. Result reports will include the reminder that a negative test result may not rule out influenza and should not affect patient management or infection control decisions.

The LA Office of Public Health Laboratory will provide information for clinicians on the use and interpretation of commercially available rapid diagnostic tests for the detection of influenza

during a pandemic, including the CDC guidance provided in the HHS national pandemic influenza plan.

As the pandemic continues, the LA Office of Public Health will provide local healthcare providers with updated guidance on which clinical specimens should be sent to the LA Office of Public Health Laboratory for testing as the needs for public health testing evolve.

Biocontainment Procedures

Biosafety conditions for safely testing specimens which may contain a novel or pandemic influenza virus are more stringent than those needed for routine testing of specimens which may contain the currently circulating seasonal influenza strains. Biosafety guidelines for handling or processing specimens or isolates of novel influenza strains are provided in the HHS national pandemic influenza plan. Briefly, testing for influenza using either commercial antigen detection assays such as EIA or nucleic acid amplification by RT-PCR can be conducted under BSL-2 containment conditions if a Class II Biological safety cabinet is used. Virus culture should not be performed except within a BSL-3 laboratory with enhancements. In addition, culture of any novel influenza virus should be kept separate from laboratory areas where seasonal influenza A viruses (i.e. H1 and H3) are cultured. Therefore, respiratory virus cultures from specimens which may contain a novel influenza virus should not be performed in most clinical laboratories. Moreover, highly pathogenic avian influenza A (H5) and A (H7) viruses are classified as select agents and any laboratory working with these agents must be certified by the USDA.

The LA Office of Public Health Laboratory consists of BSL-2 laboratories except for a BSL-3 laboratory at the Shreveport Regional Laboratory. This LA Office of Public Health Laboratory is registered with the CDC and USDA to handle select agents. At the present time, the LA Office of Public Health Laboratory testing for novel influenza subtypes is by real time RT-PCR, but not by virus culture. At the LA Office of Public Health Laboratory, storage of these specimens and processing to prepare nucleic acid extracts is performed in the BSL-2 laboratory. The LA Office of Public Health Laboratory testing for novel influenza will be limited to RT-PCR with confirmatory testing and virus culture done at CDC.

The LA Office of Public Health Laboratory will work with clinical and other laboratories in Louisiana to assure that they are aware of the national biocontainment guidelines for specimens from any patient who may be infected with a novel influenza virus and of the need to review their laboratory protocols to assure laboratory safety during the current novel virus alert phase and during a possible pandemic.

Occupational Health Issues for Laboratory Workers

At all times (i.e. during the Interpandemic, Pandemic Alert, and Pandemic Periods), laboratories handling specimens that possibly contain a novel influenza virus need to maintain safety practices to protect the health of laboratory workers. These safety practices include: (1) conducting laboratory procedures under appropriate biocontainment conditions, as described in the national pandemic influenza plan (2) encouraging routine influenza vaccination of all eligible laboratory personnel who are exposed to specimens from patients with respiratory infections; and (3) providing medical surveillance and follow-up for laboratory personnel who work with novel strains of influenza virus, following the national guidelines provided in the national pandemic influenza plan. Medical surveillance of laboratory personnel at risk for occupational exposure to novel influenza viruses is important for the benefit of the individual worker and is

essential to prevent transmission to other individuals within the community in the event of a laboratory-acquired infection.

Within the LA Office of Public Health Laboratory, the Laboratory Safety Officer will work with the LA Office of Public Health Laboratory administration and the laboratory manager of the virology section to perform risk assessment for novel influenza virus testing and to ensure compliance with national biosafety guidelines in the current national plan and as updated by CDC.

It is important to note that the guidelines for biocontainment and for medical surveillance of laboratory personnel apply to any laboratory which may handle or culture specimens containing novel or avian influenza viruses. Such laboratories would include not only the clinical and public health laboratories traditionally included within the Laboratory Response Network (LRN), but also research, university, veterinary, agricultural, or private industry laboratories that may not be easily reached via routine public health communications. Therefore, the LA Office of Public Health Laboratory will work to identify such laboratories within Louisiana, to set up a means for the laboratory to receive public health communications, and to provide those laboratories with information about the national guidelines, how to contact the LA Office of Public Health if possible exposure has occurred, and how to contact the LA Office of Public Health Laboratory for influenza subtype testing when indicated for evaluation of novel influenza illness in an exposed employee.

Deceleration and Resolution (Demobilization)

During the Deceleration Interval, rates of pandemic infection decline. Mitigation activities began to be lifted and recovery begins. If medical countermeasures remain available, providing medication and supplies for treatment will continue. The Lab continues its Operations throughout the deceleration process.

Recommendations for Clinical and Other Laboratories

Biosafety recommendations for all laboratories which handle influenza virus or specimens (human or animal) which may contain influenza virus (e.g. research, university, veterinary, agricultural, industry, military, hospital/other clinical, and public health laboratories):

1. Review the laboratory biosafety portions of the HHS National Pandemic Influenza Plan (www.pandemicflu.gov) within the Laboratory Diagnostics section (Supplement 2): (1) Biocontainment procedures and (2) Occupational health issues for laboratory workers.

2. Perform a risk assessment for influenza biosafety within the laboratory. Create a laboratory specific plan to meet the pertinent HHS guidelines for biosafety and occupational health.

3. If the laboratory handles human or animal specimens which may contain any influenza virus not currently circulating in humans, ensure that the biosafety plan also includes the following:

• CDC and LA Office of Public Health website addresses to obtain updated influenza information
• Contact numbers for the state health departments to obtain or report information about novel influenza virus
• Contact numbers for the LA Office of Public Health Laboratory to obtain laboratory specific information.

4. Review any federal or state regulations or guidelines which apply to influenza agents or nucleic acids used within or shipped by the laboratory. Examples may include: transport of Infectious Disease materials, HHS select agents, USDA select agents, federal recombinant DNA guidelines, CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, and the Louisiana Regulations for Disease Reporting.

Diagnostic testing recommendations for clinical and public health laboratories which process human specimens for influenza testing.

1. Review the HHS national pandemic influenza plan (www.pandemicflu.gov), especially the Laboratory Diagnostics section (Supplement 2).

2. Use the national and state guidelines to create a laboratory-specific pandemic influenza
plan, including plans for the current pandemic alert period. Key actions include the following:

• If a novel influenza virus infection is suspected, the laboratory should contact the Office of Public Health Infectious Disease Epidemiology section and the Office of Public Health Laboratory to arrange for novel influenza virus testing. The hospital laboratory should NOT attempt virus isolation.
• It is essential that the laboratory be informed if clinical specimens are submitted from a patient suspected of novel influenza virus infection, to assure safe biocontainment and appropriate testing. Establish clear lines of communication with medical staff and infection control to be implemented if a novel influenza virus is suspected.
• Review procedures for communication, specimen collection, and transport to the LA Office of Public Health Laboratory for novel influenza virus testing.
• Plan for laboratory surge capacity in the event of an influenza pandemic, including issues of staffing/training, laboratory supplies/equipment, and specimen management, including an increase in specimens sent to the LA Office of Public Health Laboratory at the beginning of the pandemic. Be aware that during a pandemic, many individuals may not be able to report to work and the quantity of many supplies may become quite limited.

3. Implement and exercise the laboratory pandemic influenza plan.

During the Pandemic Period

A. Review and update biosafety precautions based on CDC and LA Office of Public Health recommendations and risk assessment within each individual laboratory.

B. Deploy resources to manage increased numbers of requests for influenza testing and for laboratory support for an increased number of patient visits related to respiratory disease.

C. Communicate freely with the state health department and stay updated about current recommendations related to pandemic influenza.

D. Follow public health guidelines to submit selected specimens to the LA Office of Public Health Laboratory for pandemic influenza testing. During the early phase of an influenza pandemic, any private laboratory which performs RT-PCR testing for the pandemic influenza strain should consult with the LA Office of Public Health Laboratory to arrange to have their results confirmed by the LA Office of Public Health Laboratory and/or CDC.

E. Provide guidance to physicians about interpretation and limitations of influenza laboratory tests, particularly the commercially available rapid diagnostic tests.

Documentation

Reporting Requirements

The LA Office of Public Health Laboratory would report cases of novel influenza immediately to the LA Office of Public Health Laboratory Director, the Office of Public Health Infectious Disease Epidemiology section and to CDC via the Emergency Response Hotline, if required.

The LA Office of Public Health Laboratory planning for pandemic influenza will include electronic reporting of influenza results to above mentioned Office of Public Health sections and submitters as the LA Office of Public Health Laboratory implements its laboratory information system (STARLIMS).

IV. Logistics Section

Specimen Collection and Submission Guidelines

Acceptable Specimens

- Nasopharyngeal swab
- Oropharyngeal swab
- Nasal swab
- Broncheoalveolar lavage
- Tracheal aspirates
- Nasopharyngeal aspirate or wash
- Oropharyngeal aspirate or wash

Collection Procedures

Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts are NOT recommended. Specimens collected with swabs made of calcium alginate are NOT acceptable. ***Check the expiration date on the viral transport media. If the transport media is expired, the specimen will be considered UNSATISFACTORY for testing.***

A. Nasal, nasopharyngeal or oropharyngeal swabs: Swab must be placed in a viral transport media and mixed well immediately after collection.

B. Broncheoalveolar lavage, tracheal aspirates, nasopharyngeal or oropharyngeal aspirates or washes: Aseptically dilute liquid sample with an equal volume of viral transport media. Portion of transport media may be removed so that the volume of the sample equals the volume of the transport media (i.e., 1:1 dilution).

Requesting Influenza Testing

Prior authorization by the Office of Public Health Infectious Disease Epidemiology section is required before submitting samples for Novel Influenza testing.

Lab 96 forms may be obtained on the OPH Laboratory's website (www.lab.dhh.louisiana.gov) or by contacting the Office of Public Health Laboratory.

The patient health care provider must complete the specimen submission form (lab 96) to request Influenza testing. ***Please fill out all forms as completely as possible with the following information or the specimen may be considered UNSATISFACTORY for testing:***

- Name of the patient
- Date of Birth
- Source of specimen
- Gender

- Date of collection
- Time of collection
- Submitter's name, address and fax number
- Unique ID or Hospital ID
- Epidemiologic risk factor
- Travel history
- Specify on the form that Influenza testing is requested

Shipping Instructions

Any suspect influenza specimen should be shipped on wet ice (2 - 4°C) as a biological substance, category B specimen. The shipper (hospital, clinic, or parish health unit) – not the transport company – is responsible for the shipment until the reaches the consignee (LA Office of Public Health Laboratory). The specimen can be shipped via FedEx, UPS, United State Postal Service (USPS) or any other Courier system. The specimen should be sent overnight. If the specimen will not reach the OPH Central Laboratory within 96 hours of collection, the specimen should be frozen (-70°C or below) and shipped using dry ice.

All specimens should be shipped to the OPH Central Laboratory.

Office of Public Health
Central Laboratory
Attn: Virology
3101 W Napoleon Ave
Metairie, LA 70001
Phone: 504-219-4664
24 hour Emergency Cell: 504-458-9537

When submitting a routine influenza specimen, there is no need of prior notification. However, the LA Office of Public Health Laboratory must be notified in advance when a specimen from a suspected novel influenza case will be arriving at the Laboratory. When a suspected novel or avian influenza specimen is received in the lab, the following internal staff should be notified verbally or by phone, email, or page: Laboratory Director, Laboratory Assistant Director, Laboratory Emergency Response Coordinator, and Molecular Technical Master.

v. Security Section

Overview

The LA DHH OPH Laboratory is staffed with a 24 hour, 7 day-a-week security guard. The building is also secured with an alarm system.

VI. Public Information Section

Overview

All information requested from the LA DHH OPH Laboratory is referred to the DHH PIO.

VII. Supporting Documentation

Table 1: Stages and Triggers for Pandemic Influenza Response

<table>
<tr><th>WHO Phase</th><th>CDC Stage</th><th>Influenza Interval</th><th>Louisiana Trigger</th><th>National Trigger</th></tr>
<tr><td>1: Low risk of human cases</td><td rowspan="2">0: New Domestic Animal Outbreak in At-Risk Country</td><td rowspan="2">Investigation of Novel Influenza A Infection in Animals and Humans</td><td>Identification of animal case of influenza A subtypes with potential implications for human health within the State</td><td>Identification of animal case of influenza A subtypes with potential implications for human health anywhere in the world</td></tr>
<tr><td>2: Higher risk of human cases</td></tr>
<tr><td rowspan="2">3: No or very limited human-human transmission</td><td rowspan="2">1: Suspected Human Outbreak Overseas</td><td>Identification of human case of potential novel influenza A infection within Louisiana</td><td>Identification of human case of potential novel influenza A infection anywhere in the world</td></tr>
<tr><td rowspan="2">4: Evidence of increased human-human transmission</td><td rowspan="3">2: Confirmed Human Outbreak Overseas</td><td rowspan="3">Recognition of Pandemic Virus</td><td rowspan="3">Confirmation of human cases of novel influenza A and demonstration of efficient and sustained human-to-human transmission within Louisiana</td><td rowspan="3">Confirmation of human cases of novel influenza A and demonstration of efficient and sustained human-to-human transmission anywhere in the world</td></tr>
<tr><td>5: Evidence of significant human-human transmission</td></tr>
<tr><td rowspan="3">6: Efficient and sustained human-human transmission</td><td>3: Widespread Human Outbreaks in Multiple Locations Overseas</td></tr>
<tr><td>4: First Human Case in North America</td><td>Initiation of Pandemic Wave</td><td>Laboratory-confirmed case of defined pandemic influenza detected within Louisiana</td><td>Laboratory-confirmed case of defined pandemic influenza detected within the US</td></tr>
<tr><td>5: Spread Throughout</td><td>Acceleration of Pandemic Wave</td><td>Two or more laboratory-confirmed cases in Louisiana that</td><td>At least one State in five of the ten FEMA/HHS regions</td></tr>
</table>

	United States		are not epi linked to any previous case; or, Increasing cases exceed resources for case-based control measures	have met the Acceleration criteria
		Peak/Established Transmission During Pandemic Wave	>10% of specimens from patients with influenza-like illness submitted to the State public health laboratory are positive for the pandemic strain during a seven day period; or, "Regional" pandemic influenza activity is reported by the LA DHH OPH using CDC surveillance criteria, or The health care system surge capacity has been exceeded	The majority of States have met the Peak/Established Transmission criteria (includes States that have transitioned into the Deceleration Interval)
		Deceleration of Pandemic Wave	<10% of specimens from patients with influenza-like illness submitted to the State public health lab are positive for the pandemic strain for at least two consecutive weeks; or, The health care system capacity is below surge capacity	The majority of States have met the Deceleration criteria (includes States that have transitioned into the Resolution Interval)
	6: Recovery	**Resolution** of Pandemic Wave	Laboratory-confirmed pandemic influenza cases are occurring sporadically; or, The healthcare system capacity is approaching pre-pandemic levels	The majority of States have met the Resolution criteria

Appendix 1: Footnotes and References

[i] World Health Organization. Recommended Use of Antivirals, Briefing Note 8. August 21, 2009. (http://www.who.int/csr/disease/swineflu/notes/h1n1_use_antivirals_20090820/en/index.html)

[ii] Centers for Disease Control. Antiviral Information and Guidance. September 23, 2009. (http://www.cdc.gov/h1n1flu/antiviral.htm)

[iii] Harper SA, Bradley JS, Englund JA, et al. Infectious Diseases Society of America Guidelines. Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America. Clinical Infectious Diseases 2009;48:1003–1032. (http://www.idsociety.org/content.aspx?id=9202#flu).

[iv] CDC Updated Guidance for Businesses and Employers for the Fall Flu Season, September 2009. (http://www.pandemicflu.gov/plan/workplaceplanning/index.html)

[v] CDC Pandemic Preparedness Planning for US Businesses with Overseas Operations Checklist, January 2007. (http://pandemicflu.gov/professional/business/businessoversea.html).

[vi] Occupational Health and Safety Administration. Guidance on Preparing Workplaces for an Influenza Pandemic, 2009. (http://www.osha.gov/Publications/OSHA3327pandemic.pdf)

[vii] CDC Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting. May 13, 2009. (http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm).

[viii] CDC Using Antiviral Medications to Control Influenza Outbreaks in Institutions. (http://www.cdc.gov/flu/professionals/infectioncontrol/institutions.htm).

[ix] Antiviral Agents for Seasonal Influenza: Side Effects and Adverse Reactions. MMWR: Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008 MMWR August 8, 2008 / 57(RR07);1-60.
(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm).

[x] Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America. (http://www.idsociety.org/content.aspx?id=9202#flu).

[xi] Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm).

[xii] State of Louisiana Emergency Operations Plan, June 2007 (http://www.ohsep.louisiana.gov/plans/EOP.pdf) with amendments a) Executive Order BJ 08-32 - Emergency Operations Plan (http://www.ohsep.louisiana.gov/proclamations/exorder200832.htm) and b) Executive Order BJ 08-94, Amendment to Executive Order No. BJ 08-32- Emergency Operations Plan (http://www.ohsep.louisiana.gov/proclamations/exorder200832_amendment.htm)

[xiii] United States Department of Homeland Security, Federal Emergency Management Agency, National Response Framework, January 2008. (http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf)

[xiv] DHH OPH Organizational Chart. Last updated 03/2009. (http://www.dhh.louisiana.gov/offices/publications/pubs-1/OPH%20Org%20for%20Website.pdf)

[xv] FEMA ICS Form 308 (http://www.fema.gov/emergency/nims/JobAids.shtm)

[xvi] NIMS ICS template forms comprising IAP. (http://www.fema.gov/emergency/nims/JobAids.shtm)